

DATE: December 11, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: ^{ASG} A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Atlas Operations Inc Recall

SUGGESTED

ACTION: Unclassified Recall; The active drug ingredient is not listed on the product label; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. These products are currently being sold as a dietary supplement throughout the U.S. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Atlas Operations, Inc. Issues a Nationwide Voluntary Recall of Specific Lots of Sexual Enhancement Products Marketed as Dietary Supplements

Contact Person:
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FOR IMMEDIATE RELEASE – December 11, 2009 – Pompano Beach, FL – Atlas Operations, Inc. announced today that it is conducting a voluntary nationwide recall of the company's dietary supplements for sexual enhancement sold under Lot Numbers 494, 520C, 520B, 520A, 520, 521, 705, 706, 779 & 807.

These products are currently being sold as a dietary supplement throughout the U.S. Atlas Operations, Inc. is conducting a voluntary recall after being informed by the Food and Drug Administration (FDA) that a lab analyses found that the products tested from certain batches of the following products Rock Hard T12-705-09, R52-705-09, 72 hrs B54-708-09, Stamin It R2-705-08, Finally On Demand R26-706-09, R27-706-09, Sexual Surge H49-705-09, Staminil T25,705-09, Virect T29-705-09 contain Sulfoildenafilafil, an analogue of Sildenafilafil, an FDA-approved drug used as treatment for male Erectile Dysfunction (ED) making these products an unapproved drug. The active drug ingredient is not listed on the product label.

The undeclared ingredient may pose a threat to the consumer because the interaction of the analogue with some prescription drugs (such as nitroglycerin) may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take other prescription drugs. Erectile Dysfunction is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

Dietary Supplements Sold Under Lot Numbers

Lot Number ###-494-##		
Brand Name	Packaging	Expiration Date
Aspire One	Capsules, all counts	All Dates
Lot Number ###-520C-##		
Brand Name	Packaging	Expiration Date
Sex Enhancer	Capsules, all counts	All Dates
Lot Number ###-520B-##		
Brand Name	Packaging	Expiration Date
Staminil	Capsules, all counts	All Dates
Sexual Surge	Capsules, all counts	All Dates
Love Fuel	Capsules, all counts	All Dates
Lot Number ###-520A-##		
Brand Name	Packaging	Expiration Date
Staminil	Capsules, all counts	All Dates
Sexual Surge	Capsules, all counts	All Dates

Love Fuel	Capsules, all counts	All Dates
Lot Number ###-520-##		
Brand Name	Packaging	Expiration Date
Vaxitrol	Capsules, all counts	All Dates
Lot Number ###-521-##		
Brand Name	Packaging	Expiration Date
Love Fuel 2	Capsules, all counts	All Dates
Lot Number ###-705-##		
Brand Name	Packaging	Expiration Date
Erexa	Capsules, all counts	All Dates
Zenerect	Capsules, all counts	All Dates
Arousin	Capsules, all counts	All Dates
72 Hours	Capsules, all counts	All Dates
Bulk- Unlabeled	Capsules, all counts	All Dates
Enhancement	Capsules, all counts	All Dates
Red Hot Sex	Capsules, all counts	All Dates
Sexual Surge	Capsules, all counts	All Dates
Libiplus	Capsules, all counts	All Dates
Erexxx	Capsules, all counts	All Dates
Tacktol	Capsules, all counts	All Dates
Amour for him	Capsules, all counts	All Dates
Erousa	Capsules, all counts	All Dates
Rockhard	Capsules, all counts	All Dates
Staminil	Capsules, all counts	All Dates
Ezerex	Capsules, all counts	All Dates
Topviril	Capsules, all counts	All Dates
Vierect	Capsules, all counts	All Dates
APL	Capsules, all counts	All Dates
Clyamax	Capsules, all counts	All Dates
Lot Number ###-706-##		
Brand Name	Packaging	Expiration Date
Love Fuel	Capsules, all counts	All Dates
Rainbow Rocket	Capsules, all counts	All Dates
Finally On Demand	Capsules, all counts	All Dates
Xtremexcite	Capsules, all counts	All Dates

Whatzup	Capsules, all counts	All Dates
Lot Number ###-807-##		
Brand Name	Packaging	Expiration Date
Depth Charge	Capsules, all counts	All Dates

**Lot numbers may or may not contain dashes. The first three and last two digits and letters are insignificant.

***If you have a product with a different name but the same lot number please contact Atlas Operations, Inc. for recall instructions.

Our laboratories have identified that one of the raw ingredients was tainted with Sulfoildenafil. Atlas Operations takes this recall very seriously and recommits to the diligent work required in ensuring its products remain free of any potentially unapproved chemicals. We take the utmost pride in our products' quality control without compromising our customer's health.

We urge consumers who have purchased these products to discontinue their use and return to their place of purchase. You may also return products directly to Atlas Operations. Customers can call Atlas Operations at 1-800-466-4444 Monday through Friday from 9:00 am - 5:00 pm EST for instructions on the return and refund process.

It is the position of Atlas Operations, Inc. that we did not in any way knowingly or intentionally violate the law with regard to the distribution of these products.

Adverse reaction or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax. Online: www.fda.gov/MedWatch/report.htm. Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form. Fax: 1-800-FDA-0178.